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By ECF and Hand Delivery

Hon. J. Curtis Joyner
United States District Court for the Eastern District of Pennsylvania
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Re: ***Pfizer Inc. v. Johnson & Johnson et al.*****, 2:17-cv-4180 (E.D. Pa.)**

Dear Judge Joyner:

We represent Defendants Johnson & Johnson and Janssen Biotech, Inc.(collectively, "Janssen") in the above-captioned action. Enclosed is a courtesy copy of the Corrected Memorandum of Law in Support of Defendants' Motion to Dismiss. The memorandum filed last week (ECF No. 27) did not accurately describe how "Average Sales Price," a government pricing term, can be calculated. We have corrected those references on three pages of the brief and apologize to the Court for the oversight on our part.

Respectfully submitted,

William F. Cavanaugh / JHH

William F. Cavanaugh

cc: All counsel of record (*by ECF*)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,

Plaintiff,

vs.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

Defendants.

Civil Action No. 2:17-cv-4180 (JCJ)

CORRECTED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively "Janssen") respectfully submit this corrected memorandum of law in support of their motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), Pfizer Inc.'s ("Pfizer") complaint.

PRELIMINARY STATEMENT

Disappointed with the sales of its recently launched biologic Inflectra, Pfizer now seeks to blame Janssen for the drug's lack of success rather than its own apparently meager efforts to compete. Pfizer's complaint is long on its alleged grievances against Janssen and the discounts and rebates Janssen has offered. But the complaint carefully avoids addressing what Pfizer has actually done or could have done to try to convince payors (like health care insurers such as Aetna and Cigna) to include Inflectra on their formularies and to encourage medical providers (like hospitals and physicians) to use Inflectra, among the wide range of other immunology drugs (including Remicade) approved by the Food and Drug Administration ("FDA"). Instead, Pfizer seeks to dictate and circumscribe the nature of the price incentives Janssen can offer in order to reduce the degree to which Pfizer would have to price compete and cut into its own profits.

There are multiple, obvious explanations for why Inflectra may not yet have more sales. Pfizer's complaint recognizes that (1) Remicade has a long and successful clinical history with which physicians and payors are familiar, whereas biosimilars like Inflectra do not; (2) the FDA has not deemed Inflectra to be interchangeable with Remicade; (3) Remicade is cost-effective and widely covered due in part to the rebates and discounts that Janssen provides to payors and providers; (4) the FDA has approved several drugs for the treatment of the same indications as Inflectra, and Inflectra must compete against all of these drugs, including Remicade, to succeed; and (5) the entire concept of a "biosimilar" is new, with the first biosimilar approval in 2015, so physicians are not familiar with them. Pfizer's complaint ignores the consequences of these factors, which cut against the rapid adoption of Pfizer's biosimilar drug Inflectra.

The Supreme Court has made clear that the antitrust laws do not exist to protect competitors such as Pfizer from vigorous competition—particularly price competition. They exist to protect the competitive process. Consequently, an antitrust plaintiff must allege sufficient facts demonstrating that its alleged injury is the type the antitrust laws were designed to remedy and that the harm plausibly flows from the defendants' alleged anticompetitive conduct. In short, the antitrust laws do not exist to remedy an injury of the plaintiff's own making by its unwillingness to compete.

As detailed below, Pfizer has not pled *facts* (as opposed to conclusory allegations) showing that Janssen's discounts and rebates, rather than Pfizer's own unwillingness to offer lower prices on Inflectra or bundled discounts on Pfizer's many profitable, billion-dollar products, are the cause of Inflectra' s alleged poor record to date. Without such facts, Pfizer cannot plausibly plead that the cause of its alleged harm has been Janssen's competitive strategy. Hence, the complaint fails to adequately plead antitrust injury or harm to competition, and therefore does not meet the pleading requirements in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). Pfizer's claims fail for two distinct reasons:

First, the complaint is silent on whether Pfizer has sought to compete against Janssen by offering bundled discounts on its own wide range of pharmaceutical products. As one of the world's largest pharmaceutical companies, Pfizer certainly has the capacity to do so. Pfizer's burden to plead harm to competition and antitrust injury due to Janssen's practices is particularly critical where there are multiple alternative explanations for why payors and providers might not rapidly adopt Inflectra. The absence of facts alleged in the complaint addressing this issue requires dismissal because there is an insufficient nexus between the alleged anticompetitive

conduct and Pfizer's alleged harm. It is just as plausible that Pfizer's failure to offer competing bundles (as well as the other factors described above) has caused providers and payors to decline to adopt Inflectra to the degree Pfizer apparently desired.[1]

Second, there is another crucial element missing in the story Pfizer tells in its complaint. Pfizer does not plead whether it has actually offered a lower *net price* to payors on Inflectra than the *net price* to payors that Janssen has offered on Remicade, *after all discounts and rebates are taken into account*. Nor has it pled facts demonstrating that it is incapable of doing so. Pfizer only alleges that it offered a modest discount on Inflectra versus Remicade's list price by introducing Inflectra at a list price of 15% off Remicade's *list* price. But the complaint says little to nothing about whether or to what extent Pfizer has offered discounts and rebates sufficient to compete with Remicade to payors, the powerful healthcare insurers that require pharmaceutical companies to compete on price to gain preferred status on their formularies of approved drugs for their insureds.

Pfizer attempts to distract the Court with the allegation that the "list price" for Remicade has increased. But as Pfizer is well aware, the list price known as Wholesale Acquisition Cost ("WAC") *does not* take into account rebates or discounts to providers or payors, and the Average Sales Price ("ASP") reported by the government does not reflect current rebates or discounts on Remicade. ASPs are based on blended annual averages of rebates and discounts, meaning the ASPs cited by Pfizer are based in part on rebates and discounts as they existed prior to the launch

[1] Pfizer attacks two alleged forms of "bundled" discounts that Janssen allegedly offers. The first are discounts on Remicade bundled with discounts on other Janssen pharmaceutical products. It also alleges that Janssen "bundles" rebates and discounts for Remicade that apply to both use by stable patients who are responding favorably to treatment with Remicade (the so-called "incontestable patients") and new patients who could be prescribed Remicade, Inflectra or another immunology drug (the so-called "contestable patients"). This novel antitrust theory was rejected the only time it has been presented to the Third Circuit. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 406 (3d Cir. 2016). But the Court need not reach that issue on this motion.

of Inflectra. Nor do ASPs isolate the rebates given to payors to secure the preferred formulary position Pfizer complains about. Consequently, Inflectra and Remicade's WACs and ASPs do not disclose whether the net price of Inflectra to payors is currently higher or lower than the net price of Remicade. Noticeably absent in the complaint are factual allegations that the discounts and rebates Pfizer offered when it launched Inflectra resulted in a lower *net price* for Inflectra to payors compared to Remicade. It is at least equally plausible that Pfizer's failure to offer a lower net price is responsible for the alleged failure of payors to prefer Inflectra over Remicade on their formularies. As in the case of the complaint's failure to address Pfizer's efforts to offer competing "bundles" of discounts and rebates, Pfizer's failure to plead facts showing that it offered payors a lower net price requires dismissal.

In response, Pfizer will likely point to its allegation that it offered discounts off Inflectra's list price. But Pfizer does not allege that its net price to payors for Inflectra was lower than the net price (as opposed to the ASP or WAC) for Remicade. Pfizer also might point to its conclusory allegations that any competition would be futile because matching Remicade's bundled discounts and rebates would take Inflectra below Pfizer's cost of producing the drug. No facts supporting that conclusory allegation are provided in the complaint, and conclusory allegations are not sufficient to support a claim. Further, the complaint is silent on whether Pfizer could offer discounts across its portfolio of multi-billion-dollar products that could match those offered by Janssen without having to sell below its costs.

Pfizer's complaint should be dismissed for failure to plead facts sufficient to state a claim.

STATEMENT OF ALLEGED FACTS

I. REMICADE, INFLIXIMAB BIOSIMILARS, AND OTHER COMPETING DRUGS

A. Remicade and its established history in the market helping patients

Janssen launched Remicade, the innovative form of *infliximab*, in 1998 for the treatment of Crohn's disease. Compl. ¶ 38. Remicade suppresses the body's inflammatory response to human tumor necrosis factor and thus can treat a variety of autoimmune diseases. *Id.* ¶¶ 35–36. Since its launch, Remicade has been approved to treat a number of additional conditions, including rheumatoid arthritis, ulcerative colitis, and plaque psoriasis. *Id.* ¶¶ 35, 83. It now has a 19-year-long track record with payors, providers and patients. *Id.* ¶¶ 2–3, 38–39.

B. Biosimilars and other products that treat the same indications as Remicade

Remicade is a biologic, which is a term that refers to drugs that are grown in living cells. *Id.* ¶¶ 1, 28. Biologics are "complex mixtures that are not easily identified or characterized" and are vastly more complex than traditional drugs "which are chemically synthesized and whose structure is known," making it impossible to manufacture bioequivalent "generic" copies of biologics. *Id.* ¶¶ 28–29. Recognizing this, Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA") in 2010. *Id.* ¶¶ 4, 32. The BPCIA provides a pathway for companies to enter the market with biologic drugs that the FDA concludes are biosimilar to innovator biologic drugs. *Id.* ¶¶ 32–33. Inflectra is among the first biosimilars to launch in the U.S.—the very first biosimilar (unrelated to *infliximab*) was approved only in 2015. *Id.* ¶ 4. The FDA approved Pfizer's Inflectra biosimilar on April 5, 2016, and Pfizer began shipping the drug in November 2016. *Id.* ¶ 5.

Unlike generic drugs, simply because the FDA has found a biologic to be biosimilar to an innovator biologic, that does not mean it is "interchangeable" with the innovator biologic and can automatically be substituted for the innovator biologic without the physician prescriber's

approval. *Id.* ¶ 34. The BPCIA provides a mechanism for biosimilar drugs to be designated as interchangeable, which would allow substitution without the intervention of a doctor, but Inflectra has not secured such a designation. *Id.*

Many other biologic and non-biologic drugs are approved to treat the same indications as Remicade. Another *infliximab* biosimilar sold by Merck & Co., Renflexis, was launched in the United States in July 2017. *Id.* ¶ 99. And, as Pfizer acknowledges in its complaint, in addition to the infusion products, a number of non-infusion products like oral medications and injectables (such as Humira and Enbrel) are "indicated to treat the Relevant Indications" for which Remicade is approved. *Id.* ¶ 86. Enbrel and Humira are as or more successful than Remicade, with combined sales that eclipse Remicade's sales many times over.[2]

II. DISTRIBUTION OF AND REIMBURSEMENT FOR INFUSION DRUGS SUCH AS REMICADE AND INFLECTRA

As infusion products, Remicade and Inflectra are distributed to hospitals and private physicians that operate infusion centers that administer the drugs to patients suffering from an indicated medical condition. Compl. ¶ 87. These providers purchase the drugs to administer them to patients. *Id.* ¶ 89.

Every branded prescription drug has a published WAC, often known as the list price for the drug. *Id.* ¶ 5 & n.1. For drugs administered by a health care provider, such as infusion drugs, as Pfizer alleges, manufacturers may offer these providers discounts and rebates off of WAC to incentivize the provider to utilize the drug if appropriate for a patient. *Id.* ¶¶ 74, 76. Whether it

[2] In the second quarter of 2017, for example, Remicade's sales in the United States were $1.064 billion. *See* Ex. A (Johnson & Johnson Quarterly Earnings Release for Q2 2017) at 7. Enbrel sales for the same quarter in the United States were $1.411 billion, and Humira sales were $3.201 billion. *See* Ex. B (Amgen 10Q for Q2 2017) at 29 (Enbrel); Ex. C (AbbVie 10Q for Q2 2017) at 25 (Humira). The Court may take judicial notice of revenue information contained in SEC statements and in company earnings releases. *See In re Astea Int'l Inc. Sec. Litig.*, 2007 U.S. Dist. LEXIS 58238, at *18 n.5 (E.D. Pa. Aug. 8, 2007) (citing *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002)).

is a hospital or an infusion center administering a drug such as Remicade, all of these entities seek to be reimbursed for their efforts. *Id.* ¶¶ 50, 89.

Health care insurers (often referred to as payors) reimburse these entities based on contracts negotiated with the providers. *Id.* ¶¶ 50, 54. As Pfizer alleges, healthcare insurers also create what are known as formularies, which are lists of drugs for which the healthcare payor has agreed to provide reimbursement. Many times these formularies have different tiers with certain drugs listed as "preferred" drugs. *Id.* ¶ 52. Pharmaceutical companies, such as Pfizer and Janssen, compete for preferred status on a payor's formulary, in part, by offering the payor rebates and discounts. *Id.* These reduce the net price the payor is ultimately paying for reimbursement of a Pfizer or Janssen drug.

III. PFIZER'S MARKETING STRATEGY FOR INFLECTRA

Pfizer, one of the largest pharmaceutical companies in the world, is a "research-based international pharmaceutical company which researches, develops, manufactures, and sells pharmaceutical products across the spectrum, from branded innovator products to generics and over-the-counter medications." Compl. ¶ 18. Pfizer markets a variety of blockbuster drugs, with nine of its drugs each generating over a billion dollars in annual revenue as of last year.[3] Pfizer has a market capitalization of over $200 billion. *Id.*

Pfizer alleges that when it launched Inflectra, Pfizer "set its initial list price, often referred to as the wholesale acquisition cost (or 'WAC'), at 15 percent below the then-current WAC of Remicade." *Id.* ¶ 5. As the complaint alleges, "WAC is the manufacturer's published list price to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price." *Id.* ¶ 5 n.1. Pfizer does not specify, however, what additional

[3] *See* Ex. D (Pfizer 2016 Annual Review) at 5.

rebates or discounts it offered to payors or providers off of Inflectra's WAC price, including whether it made any attempts to offer bundled discounts across the range of pharmaceuticals that it sells.

Pfizer also alleges that Remicade's ASP has increased since Inflectra was launched and was higher as of September 2017. *See id.* ¶ 13 ("Remicade's 'average selling price' ('ASP')—which by federal law is the average of a drug's pricing after taking into account discounts, rebates, and other price concessions—actually has increased since Inflectra's entry. As of September 2017, Remicade's ASP was more than 10 percent higher than Inflectra's ASP."). Pfizer's reference to Remicade's ASP purposefully ignores two things. First, this does not take into account how ASP is calculated. Reported ASPs, such as the September 2017 ASP cited by Pfizer, are actually based on Remicade sales that occurred two quarters (*i.e.*, six months) previously. *Id.*; 42 C.F.R. § 414.804(a)(5). But even more importantly, the Remicade rebates and discounts applied to those sales would be an average of the rebates and discounts paid during that earlier quarter and the nine months before that quarter. 42 C.F.R. § 414.804(a)(3). Thus, the ASPs cited by Pfizer include discounts and rebates for periods even before Inflectra's launch. *See id.* ¶ 5 ("Pfizer began shipping Inflectra in November 2016 … ."). Second, ASP does not reflect the net price to payors because the calculation of ASP does not isolate the price reductions attributable to discounts and rebates to payors specifically. *See* 42 C.F.R. § 414.804(a)(1) (noting that ASP is calculated using "manufacturer's sales to *all* purchasers") (emphasis added). As Pfizer itself alleges, Janssen offers providers and payors "attractive rebates on all Remicade prescriptions" and after Inflectra was launched "began offering certain large providers additional rebates and/or discounts." *Id.* ¶¶ 66, 74. Yet, Pfizer is silent about what specific set of discounts

and rebates Pfizer has offered to payors in order to seek favorable treatment on the formularies of healthcare insurers.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), for a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In evaluating the sufficiency of a complaint, a court must accept all well-pleaded allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party. *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011). Courts are not required, however, to credit bald assertions or legal conclusions improperly alleged in the complaint. *Id.*

As the Supreme Court has made clear, under these standards it is insufficient for a plaintiff to plead "facts that are 'merely consistent with'" liability. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). A plaintiff instead must go beyond, and plead facts that show that liability is not only possible, but that "nudge [the] claims . . . across the line from conceivable to plausible." *Id*. at 680.

I. PFIZER IS REQUIRED TO ALLEGE SPECIFIC FACTS SHOWING THAT IT HAS SUFFERED ANTITRUST INJURY AND THAT JANSSEN'S REBATE AND DISCOUNTING PRACTICES HARMED COMPETITION

Unless Pfizer pleads facts showing how it has attempted to compete with Janssen, Pfizer's complaint fails to state a claim. The law applicable to Pfizer's Section 1 and Section 2 claims under the Sherman Act and its Section 3 claim under the Clayton Act is effectively the same. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 n.11 (3d Cir. 2016). Among other elements of its claims, Pfizer must plead facts showing that Janssen "engaged in anticompetitive conduct and that [Pfizer] suffered antitrust injury as a result." *Id.* at 402; *see*

also W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 101 (3d Cir. 2010) ("[A]n antitrust plaintiff must do more than show that it would have been better off absent the violation; the plaintiff must establish that it suffered antitrust injury.").

Antitrust injury is an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). A mere causal link between some form of injury to a plaintiff and a defendant's conduct is insufficient to meet this requirement; rather, a plaintiff is required to demonstrate an injury that is specifically attributable to "a competition-reducing aspect or effect of the defendant's behavior." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990). In other words, an antitrust injury "should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick*, 429 U.S. at 489; *see also Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 486 (3d Cir. 1992) (plaintiff must plead "a plausible theory of causation of 'injury of the type the antitrust laws were designed to prevent'") (quoting *Brunswick*, 429 U.S. at 489).

The antitrust injury requirement ensures "that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place." *Atl. Richfield*, 495 U.S. at 342. It also prevents plaintiffs from using the antitrust laws to compensate them for harms that are "inimical" to the antitrust laws, such as those resulting from vigorous price competition. *See Brunswick*, 429 U.S. at 488. Antitrust injury is a threshold question, and a plaintiff's failure to allege it requires dismissal. *See, e.g., SigmaPharm, Inc. v. Mut. Pharm. Co.*, 454 F. App'x 64, 66 (3d Cir. 2011) (affirming district court's dismissal of antitrust claim for lack of antitrust injury); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d Cir.

1998) (same); *Schuylkill Energy Res., Inc. v. Penn. Power & Light Co.*, 113 F.3d 405, 410 (3d Cir. 1997) (same).

Consistent with this principle, it is a fundamental precept of the antitrust laws that they "are concerned with 'the protection of competition, not competitors.'" *Eisai*, 821 F.3d at 398–99 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962)). Accordingly, a plaintiff must also be able to show that "competition, not merely competitors, has been harmed." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005); *see also ZF Meritor LLC v. Eaton Corp.*, 696 F.3d 254, 347 (3d Cir. 2012) (same). Pfizer may not like having to compete with Janssen, but there is no antitrust remedy for a competitor who has been subjected to robust competition.

II. PFIZER CANNOT SHOW IT SUFFERED AN ANTITRUST INJURY BECAUSE IT FAILS TO PLEAD FACTS SHOWING THAT IT ACTUALLY ATTEMPTED TO COMPETE

In its complaint, Pfizer claims that Janssen has foreclosed Pfizer from the market by inducing payors and providers to prefer the use of Remicade over the use of Inflectra. In general, Pfizer complains that Janssen has agreed to provide rebates and discounts for the use of Remicade as well as other Janssen products:

- "In short, insurers that decline J&J's offer face a substantial financial penalty, and those that accept receive a payoff (multimillion dollar rebate payments) in return for their commitment to exclude biosimilars." (Compl. ¶ 9).
- "In most cases these coercive biosimilar-exclusion contracts were the only economically viable option for insurers—as adopting any alternative would require the insurer to incur a substantial penalty (i.e., foregone rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term." (*Id.* ¶ 64).
- "After Inflectra's introduction, J&J began offering certain large providers additional rebates and/or discounts on Remicade, but only if the provider committed to buy Remicade for nearly all of its infliximab needs." (*Id.* ¶ 74).

Pfizer recognizes that one common form of competition in the pharmaceutical industry is offering rebates and discounts to obtain favored status from payors and providers over other

competing therapeutic options (with the result that the payors (and ultimately patients) benefit from lower drug costs). *See id.* ¶ 52 ("Drug manufacturers compete, usually with rebates or other price concessions, to obtain coverage under insurer medical policies and to have either fewer restrictions on reimbursement than their competitors—or, at a minimum, to achieve 'parity' whereby the competing products have the same restrictions on reimbursement and the patient and/or doctor can choose between them.").

Despite this admission that rebate and discount competition is standard practice in the pharmaceutical business, Pfizer simply alleges, in conclusory fashion, that it cannot compete with the "total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts," and declares in equally conclusory fashion that "competition to Remicade is foreclosed." *Id.* ¶ 78. Pfizer does not plead any specific facts to show how it actually tried to compete with Janssen through its own use of rebates and discounts. Its pleading is therefore fundamentally deficient, in at least two respects.

A. Pfizer fails to allege it tried to compete using multi-product bundles

There is a striking omission in Pfizer's complaint. While Pfizer talks at length about Janssen's "bundled discounts," Pfizer is silent on whether it has offered similar discounts and rebates on its own products to compete with Remicade—particularly to payors. Pfizer—one of the largest pharmaceutical companies in the world—never alleges that it is incapable of offering competitive bundled discounts across its product lines. *See, e.g., id.* ¶¶ 9, 75.

Merely pleading that Janssen offered bundled discounts, without more, is insufficient to state a claim. There is nothing presumptively unlawful about bundled discounts, which often offer the ultimate procompetitive benefit—lower prices. *See, e.g.*, *Eisai*, 821 F.3d at 404 (bundled discounts only inappropriate where they deprive another party of any meaningful

choice between competing products). Here, Pfizer fails to plead why it was incapable of offering competing bundled discounts or rebates.

The issue of bundled discounts was raised in *Lepage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003). On the specific facts before it, the Third Circuit held that "exclusive dealing and bundled rebates . . . can sustain a verdict under § 2." *Id.* at 144, 152. Importantly, in *Lepage's*, the plaintiff, unlike the defendant 3M, did not have access to a broad array of products and therefore could not offer a competing bundled discount. In recognition of this fact, the Third Circuit in *Esai* specifically noted that it had "limited the reasoning in *LePage's* 'to cases in which a single-product producer is excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across multiple different product lines.'" 821 F.3d at 405 (quoting *ZF Meritor*, 696 F.3d at 274 n.11); *see also id.* at n.35 ("While *LePage's* remains the law of this Circuit, it has been the subject of much criticism.").

Indeed, other courts that have examined similar facts have found that, where a party can offer its own bundle, it has no claim against a competitor for anticompetitive bundling. *See, e.g.*, *Invacare Corp. v. Respironics, Inc.*, 2006 U.S. Dist. LEXIS 77312, at *34–35 (N.D. Ohio Oct. 23, 2006) (noting that no "court has found a bundling practice anticompetitive" where plaintiff "can sell a similar bundle"); *Applied Med. Res. Corp. v. Ethicon, Inc.*, 2006 U.S. Dist. LEXIS 12845, at *9 (C.D. Cal. Feb. 2, 2006) (explaining that bundling has never been found to be unlawful where a "challenger had an opportunity to compete for the bundle" or "a competitor offered a similar bundle"). Pfizer accordingly should have pleaded facts to make plausible its claim of injury that demonstrate that it somehow could not offer a bundle drawn from its own broad product line. It has not pled such facts, and its unwillingness to offer a competing bundle

in order to avoid offering lower prices (and perhaps earn lower profits) on its other products is not a defense.

There can be no dispute that Pfizer is one of the world's largest pharmaceutical companies with a broad range of billion-dollar drug products. Pfizer's omission of allegations regarding its own inability (as opposed to its unwillingness) to offer bundled discounts is all the more striking given Pfizer's allegations that discounts and rebates are a primary method of competition between manufacturers. Without alleging that it actually tried to compete with Janssen on this basis, Pfizer has failed to allege facts indicating that its lack of success in the market is due to the alleged anticompetitive behavior by Janssen, as opposed to its own failure to engage in competition. This is particularly relevant because the antitrust laws encourage competitive conduct that lowers the prices of products to the benefit of purchasers. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) ("Low prices benefit consumers regardless of how those prices are set.").

Pfizer's omission of allegations regarding its own competitive efforts is particularly suspicious in light of its admissions regarding multiple other factors that, on their own, could explain Inflectra's lack of success. Pfizer admits that Remicade has a clinical history of nearly two decades, and that it has been highly successful in treating multiple indications, giving providers ample time to become familiar with and to rely on Remicade. Compl. ¶¶ 2–3, 39, 83. In contrast, Inflectra has been on the market for barely a year. *Id.* ¶ 5. And Pfizer admits that Inflectra has not been designated as "interchangeable" with Remicade. *Id.* ¶ 34 & n.10. Providers are therefore required to make an affirmative decision to switch existing patients from Remicade to Inflectra. Further, the entire category of biosimilars is new, with the first one

approved only in 2015, so physicians and others in the health care industry are still learning about biosimilars and are almost certainly cautious in their initial approaches.

In light of these admissions, under *Iqbal* and *Twombly*, Pfizer has simply failed to allege facts that nudge its claim across the line from conceivable to plausible.

Twombly itself is instructive. In *Twombly*, the local exchange carrier defendants allegedly all engaged in conduct that resulted in overcharges and poor service for customers of competing exchange carriers. Plaintiffs alleged that the local exchange carriers did so to sabotage the business prospects of the competing exchange carriers, and further alleged, in a general fashion, that the defendants conspired with one another. 550 U.S. at 550–51. But plaintiffs did not plead any specific facts supporting the existence of the alleged conspiracy, as opposed to the conduct that caused them injury. The Supreme Court found that the allegations of parallel conduct by the local exchange carriers, although "consistent with conspiracy," was "just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market." *Id.* at 554. The Supreme Court directed dismissal of the case for failure to plead sufficient facts that made a showing of liability plausible, rather than possible. *Id.* at 570. Pfizer's complaint should meet the same result here.

This shortcoming in Pfizer's complaint exists regardless of whether Pfizer's Sherman Act claims are analyzed under a "rule-of-reason" or a "price-cost" test. The former assesses whether the anticompetitive effects of the alleged conduct outweigh the procompetitive effects. *See ZF Meritor*, 696 F.3d at 268. The latter focuses on whether the defendant's pricing satisfied the predatory pricing standards articulated in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993), which looks to whether the defendant discounted below cost with a reasonable expectation of recouping those lost profits once the competitive threat is eliminated.

See ZF Meritor, 696 F.3d at 269, 271 (citing *Brooke Group*). The Court need not resolve on this motion which legal test should apply to the alleged conduct Pfizer has challenged[4] because the failure to plead antitrust injury or harm to competition is an essential element of any Sherman Act claim. *See Eisai*, 821 F.3d at 398–99, 402.

Here, by failing to plead that it is unable to compete with Janssen by offering its own bundled discounts, Pfizer falls short of demonstrating that it has suffered antitrust injury due to Janssen's conduct or that the lower prices resulting from Janssen's bundled discounts and rebates have resulted in harm to competition.

B. Pfizer fails to allege it has offered competitive prices for Inflectra over Remicade

In addition, Pfizer has failed to allege facts showing that it has offered net prices on Inflectra to payors that were lower than Remicade's or facts showing that it has been incapable of doing so—as opposed to unwilling to do so. Central to Pfizer's complaint are allegations that Janssen has entered into contracts with payors (such as Aetna, Cigna, and United Healthcare) to provide rebates and discounts in exchange for favorable formulary treatment for Remicade over Inflectra. *See supra* at 6–7. But while Pfizer has included vague and conclusory allegations that it is "prepared to negotiate with *providers* to make Inflectra the lower-price infliximab," (Compl. ¶ 76 (emphasis added)), it does not make similar allegations that it is prepared to engage in similar negotiations with *payors*. Indeed, Pfizer rests on the allegation that it set the list price (*i.e.*, the WAC) for Inflectra below that of Remicade. But list price is not a meaningful metric, particularly as to payors, because it does not take into account the discounts or rebates pharmaceutical manufacturers give to payors to secure favorable formulary placement relative to competing drugs.

[4] In *ZF Meritor*, the Third Circuit noted that if the clearly predominant mechanism of competition was price competition then the *Brooke Group* price-cost test should apply. *See ZF Meritor*, 696 F.3d at 275.

Therapeutic categories with numerous alternative branded drugs typically feature significant price competition. That competition may be reflected in the WAC of competing drugs. Compl. ¶ 2 n.1. But, as the complaint recognizes, price competition also typically takes the form of discounts and rebates to market participants, such as payors and providers, that have the ability to move market share. Pfizer's reference to Remicade having a higher ASP then Inflectra is misleading. As discussed above, ASP does not reflect current pricing because of delays in reporting and because it incorporates an average of discounts and rebates for the prior year including the reporting period. Thus, the ASPs referenced in the complaint incorporated data from before Inflectra was even launched. Furthermore, ASP does not isolate the discounts and rebates given to health insurers, as opposed to providers or other purchasers. For all of these reasons, ASP does not serve as an accurate measure of whether net prices to payors are increasing or decreasing.

There are no specific facts pleaded in the complaint that indicate that Pfizer has attempted to compete for payor contracts by offering rebates and discounts sufficient to make the net price for Inflectra lower than the net price for Remicade—which is to say that there are no specific facts showing that it has attempted to compete for preferred or comparable treatment to Remicade. Pfizer's failure to plead facts showing the extent to which Pfizer has offered rebates and discounts to payors to gain favorable formulary status reveals a fundamental flaw in its complaint. By ignoring price competition among payors, Pfizer has not even alleged facts showing that Inflectra has a lower net price to payors (after all rebates and discounts) than Remicade. As discussed above, Pfizer attempts to disguise this fatal shortcoming by referring to Remicade's ASP (which does not reflect current market data or isolate payor discounts and rebates). But that tactic is transparently wrong and inadequate.

Pfizer cannot rescue the plausibility of its claim of injury by asserting in conclusory fashion that it could not compete against Remicade's net price because doing so would take Inflectra's net price below Pfizer's cost of producing Inflectra. As an initial matter, such allegations relate only to discounts on Inflectra and do not address Pfizer's ability to offer multi-product discounts as discussed above. More generally, Pfizer is not entitled to premise an antitrust violation on its refusal to compete on price to win payor contracts and then simply allege, without any facts, that it might be too costly to their bottom line to do so. *See Iqbal*, 556 U.S. at 678 (conclusory allegations are not sufficient) (citing *Twombly*, 550 U.S. at 555).

For the same reasons as with bundled discounts, Pfizer's failure to plead facts showing that it cannot offer competitive discounts to payors dooms its claims. Pfizer has not alleged a plausible antitrust injury where there are no facts that suggest it was precluded from competing for the contracts at issue. *See, e.g.*, *Methodist Health Servs. Corp. v. OSF Healthcare Sys*., 2016 U.S. Dist. LEXIS 136478, at *150 (C.D. Ill. Sept. 30, 2016) ("When the contracts are frequently available, there is no possible antitrust injury, because all parties will have the opportunity to compete."), *aff'd* 859 F.3d 408 (7th Cir. 2017).

CONCLUSION

For the foregoing reasons, Pfizer's complaint should be dismissed.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 4, 2017, I electronically filed the foregoing brief in support of Defendants' Motion to Dismiss using the CM/ECF system, which will send notification of such filing to all parties of record.

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